REMARKS

Please note that an Amendment is being filed concurrently herewith in Serial No. 09/937,584 (Docket No. SEA-6-7-US) which has the identical disclosure and is also based on PCT/US 00/08354.

It is noted with appreciation that claims 10 and 11 are allowed.

Claim 9 is cancelled.

By the foregoing, a minor amendment is made to claims 1, 10, 11, 18 and 20, changing "fluidize" to "aerosolize" for consistency. A period is added at the end of claim 16.

Favorable reconsideration of the application in its presently-amended form is requested.

"Expansive Bolus" and "Mixing Chamber"

At the outset, each of the independent claims in the case includes limitations of an "expansive bolus" and a "mixing chamber," which is also referred to in the specification as a "mixing/stilling/classification chamber." The "expansive bolus" and "mixing/stilling/classification chamber" are critical, integral, and novel elements of the aerosol generation embodiments of invention. (As noted in specification paragraph [0029], for brevity the mixing/stilling/classification chambers are generally referred to in the specification simply as "mixing chambers." These are important and significant limitations which are neither disclosed in nor suggested by the prior art.

As employed in the specification, a "bolus" may be defined as: A small volume of fluid containing useful entities which is introduced into a larger fluid volume for subsequent transport and use.

An "expansive bolus" may be defined as: A bolus, consisting of aerosol entities and gas, which is generated under conditions of higher aerosolizing and transporting gas pressure and which is subsequently allowed to expand to a lower pressure, higher volume state.

Specification paragraph [0090] ([0094] as published) includes the statement that the volume of the "expansive bolus 574 ... represents a small fraction, typically 1-10%, of the volume of mixing/stilling/classification chamber 588." (Such mixing chambers typically have volumes in the order of 1 liter = 1000 cm^3.) That statement is confirmed by the following example based on representative dimensions and operational parameters in specification paragraphs [0074] - [0076] ([0078] - [0080] as published). For simplicity, in this example most of these parameters are applied to the Microscoop embodiment of Figs. 1 - 3, paragraphs [0057] - [0067] ([0061] - [0071] as published) and to the Megadose Disc embodiment of Figs 8 and 9, paragraphs [0084] - [0093] ([0088] - [0097] as published).

Thus 250 μg = 0.25 mg of powder 125 in pocket 126 is aerosolized and transported into mixing/stilling/classification chamber 152, Fig 2, or 588, Fig 8, during a 10 ms pulsed pressurization. At the end of the 10 ms pressurization, the pressure is quickly reduced to zero by action of solenoid valve 140 (which reconnects the pressurized port to the exhaust port, typically at atmospheric pressure or 1 bar). Thus the flow at standard temperature and pressure (STP) can be substantially constant at 167 cm^3/sec during the pressure pulse and zero before and after.

During the "on time" the aerosolizing/ejecting gas, originally compressed to 10 bar, expands to ~ 1 bar in a ~ 1 liter mixing/stilling/classification chamber where its volume at

STP is of the order of 167 cm^3/sec x 0.01 sec = 1.67 cm^3. This volume is the bolus volume and the bolus contains the aerosol particles which were in the metering, powder pocket.

This example further confirms and clarifies the role of the elements required to form the expansive boli, the shape and size of the expansive boli, the initial velocity profile in the bolus (i.e., typically Vmax ~ Mach 1 ~ 340 m/s, from the pocket), and the relation of the boli to the mixing chamber and to gas flows in the mixing chamber.

There is a surprising amount of mixing and stilling provided by the mixing/stilling/classification chamber, in no way suggested by or disclosed in the prior art. That is, the variations in space and time of aerosol concentration C and gas flow Q at the input of the mixing/stilling/classification chamber are extremely high whereas we discovered that the variations in the output are, surprisingly, quite nominal, as now clarified.

For impulsive production of expansive boli, the following limits illustrate the range numerically in C and Q:

For 0.25 mg of powder at rest in a 1 mm^3 powder pocket, the C = mass/vol ~ 0.25 mg/1 mm^3 = 0.25 x 10^{-3} g/10^{-9} m^3 = 0.25 x 10^6 g/m^3 = 250,000 g/m^3. Something approaching this C occurs within the early stages of an expansive bolus, when still in or very near the pocket, upon application of a high velocity aerosolizing jet into the pocket.

As the expansive bolus moves out of the pocket and develops, but is still near the pocket, its intermediate stage volume is thus of the order ~ 1.67 cm^3 and its C ~ 0.25 mg/1.67 cm^3 = 0.25 x 10^{-3} g/1.67 x 10^{-6} m^3 = 0.15 x 10^3 g/m^3 = 150 g/m^3. The bolus volume, upon injection into the

mixing chamber volume, for this single bolus injection, is $1.67/1000 \times 100\% = 0.167\ \%$.

Thus at the bottom or input end of the mixing/-stilling/classification chamber C can vary from 0 to 1000 g/m^3 over the cross section and over ms of time. Similarly, the localized flow rate Q or flow velocity varies extremely at the input. Thus, in fact, the variations are extremely high in both space and time at the input.

For a single bolus injection of 0.25 mg into a 1 liter mixing/stilling/classification chamber, assuming perfect mixing and no wall losses, etc, the average value of C at the output is $C \sim 0.25 \times 10^{-3}/10^{-3} = 0.25\ g/m^3$, six orders of magnitude lower than the pocket and three orders of magnitude lower than in the intermediate stages of the expansive bolus, as injected into the input of the mixing chamber. Average output concentration C can, of course, be increased by insertion of multiple boli or decreased by metering smaller initial amounts of powder, etc. The surprising result referred to above is that the variations in C at the top or output end of the mixing/stilling/-classification chamber are typically within a factor of two or $\pm$ 33%.

A similar analysis applies to localized bolus flow rate or gas velocity, dropping from nearly Mach 1 ~ 340 m/sec to cm/sec from input to output.

There is an electrical analog: impulsive charging with exponential discharging of a capacitor, as in a power supply filter. The variations in current during charging can be huge while the output voltage (or current) ripple can be very small. There are formal analogs for the reservoir or energy storage of the mixing/stilling/classification chamber and

electrical capacitance. The analogs are formal because they obey the same differential equations.

The calming effect performance of the mixing/-stilling/classification chamber is described particularly in specification paragraphs [0064] and [0090] ([0068] and [0094] as published), as examples.

Paragraph [0064] ([0068] as published) reads in part: "The aerosolized powder and expanding, aerosolizing gas produce an "expansive bolus" 150 in FIG. 2 which energetically enters mixing, stilling and classification chamber 152 and disperses throughout."

Thus the powder, originally concentrated in the pocket, moves via expansive boli into the input end of the mixing chamber, and is dispersed throughout, surprisingly uniformly, by the fluid mixing (particle dispersion) and stilling (energy dispersion) processes.

Further, the energy, originally concentrated within the compressed gas as potential energy and converted to kinetic in the gas jet, is stilled or calmed. The gasdynamic conditions at the output are remarkably less variable at the output than at the wild and locally energetic input of the mixing chamber.

Paragraph [0090] ([0094] as published) reads in part: "Still referring to FIG. 8, the expansive bolus 574 resulting from such short pulses represents a small fraction, typically 1-10%, of the volume in mixing/stilling/classification chamber 588. The mixing chamber 588 thus stills and mixes the bolus just delivered with boli delivered earlier."

To summarize, the "expansive bolus" and "mixing/-stilling/classification chamber" are critical, and integral and novel elements of the aerosol generation embodiments of invention. The title of the application itself refers to "Controlled Deliveries..." The actually realized performance in

the precision of the deliveries, as measured by CVs (CV = coefficient of variation = standard deviation/mean), is enabled by the variations in C at the top or output end outputs from mixing/stilling/classification chambers being reasonably low, and much, much lower than the huge variations at the inputs just described. As stated in specification paragraph [0033], CVs of "... mass flow deliveries of about 5% and which can, in some cases, approach the order of 1%..." are experimentally realized in embodiments of the invention. Again, a surprising result is that reasonably stable values of the Q and C parameters are realized at the output of the aerosol generator system (i.e., at the output of the mixing/stilling/-classification chamber and in spite of huge variations at the input thereto associated with the expansive boli.

Overview of References

Prior to addressing the specific claim rejections, the applied references are discussed in the context of the invention.

The structure of Gerde Pat. No. 6,003,512 and that of the subject invention do have in common a powder chamber or powder pocket (applicants' terminology) for receiving powder and one or more jets for aerosolizing the powder. However, Gerde's apparatus does not meter, is "one shot" and is restricted to impulsive, exponentially-decaying jet(s) caused by fast-acting valve(s). In the aerosol generator embodiments of the subject invention, the pockets do enable metering functions. Moreover, applicants' aerosolizing and bolus-producing jets can be impulsive or continuous.

Further, as noted in applicant's previous response, the Gerde "powder chamber 12" is not a <u>metering</u> pocket. In particular, the Gerde powder chamber 12 is not <u>filled</u> with

powder Gerde column 10, lines 33-34, refers to increasing the amount loaded "from 0.05 to 0.5 mg," without changing the size of the powder chamber itself. In applicants' embodiments, the pocket itself acts as a measuring device, which determines the amount of powder to be aerosolized.

Gerde and applicants use the word bolus in their respective disclosures. However, the detailed nature of Gerde's boli and applicants' boli are different, as expained below.

The points of view about what constitutes an "aerosol generator" are also quite different. Gerde regards the apparatus that produces his aerosol bolus as the aerosol generator. Applicants regard the total system, thus including integral mixing/stilling/classification chamber, as the aerosol generator.

In further distinction, Gerde's aerosolization method requires a two-step mechanism (in the paragraph beginning in column 7, line 60) whereby the powder chamber is first pressurized and turbulent aerosolization takes place. In the second step, over a longer period of time than the compressive aerosolization, decompression takes place, whereby the gas and aerosolized powder are ejected via a small orifice. In both the pressurization and depressurization steps, the gas flow rates into and out of the powder chamber vary essentially exponentially.

Gerde also specifies a volume ratio between the high pressure gas volume (upstream of "fast-acting," "releasing" valve and the powder chamber. There is no such limitation to applicants' delivery of high pressure gas. Applicants' bolus volume is determined by the on time of a solenoid valve. The aerosol generator embodiments of the subject invention employ a substantially simultaneous, single step mechanism whereby one or more impulsive or continuous jets enter the powder pocket,

aerosolize the powder with turbulent and rotating flows (used to advantage), and eject the thus aerosolized powder from the pocket in an expansive bolus. The gas flow rate, in standard cm^3/sec, in the expansive bolus is at substantially constant flow rate, even for impulsive excitation. (For continuous excitation, the flow rates are evidently constant.) But the production of expansive boli is only part of applicants' aerosol generator. The mixing/stilling/classification section is another integral part.

Applicant's method thus enables a near-simultaneous, substantially single step aerosolization and ejection process, with substantially constant gas flow rates, to form "expansive boli," for insertion into a mixing/stilling/classification chamber, all of which, as noted above, are an integral part of embodiments of the "aerosol generator" aspects of the invention. Also as noted above, in the explanation of the surprising degree of mixing and stilling from input to output, one primary objective of applicants' invention is production of reasonably constant values of Q and C at the output of applicant's aerosol generator, for subsequent controlled mass deliveries.

Whereas applicants disclose the bolus and expansive bolus concepts and the integration of bolus generation apparatus with the mixing/stilling/classification chamber, Gerde also uses the word bolus: column/line 7/57, 9/9, 9/57 and 10/20. However, the structural elements and methods disclosed in Gerde do not allow the production of expansive boli as that term is employed by applicants Gerde shows in Fig 5 an aerosol cloud which superficially appears to be Applicant's expansive bolus. The appearance is superficial because the integrated physical structures and mechanisms by which the aerosol inputs to and

outputs from applicants' mixing/stilling /classification chamber are produced are very different, as explained above.

Gerde includes the statement beginning column 8 at line 32 that his particular structure "... allows for the fastest possible explosive expansion of the carrier gas to ambient pressure." This presumably is an explanation of the expansion required in the second, decompression step of the Gerde method. This description confirms the substantially expontial decay of the decompression flow, in contrast to applicants' substantially constant, expansive flow. Gerde is thus using different structural elements and is producing different boli than applicants. There are distinguishable differences between the meanings of "explosive expansion" and "expansive bolus;" they are not the same phenomena whatsoever.

Gerde discloses in Fig 7 ejection of aerosolized powder plus carrier gas into a syringe but this should not be construed as equivalent to Applicant's mixing/stilling/-classification chamber. It is not difficult to imagine that this syringe would have large piston face and wall losses, since it is not a properly integrated mixing/stilling/classification chamber. Gerde's results in Example 1, beginning at col 10/line 5, confirm these losses.

Accordingly, Gerde's aerosol cloud in Fig 5 and his "explosive expansion" are not Applicant's expansive bolus. Nor are Gerde's output conduits or his syringe collector equivalent to or anticipatory of Applicant's mixing/stilling/classification chamber.

Century Pat. No. 5,570,686 discloses an apparatus for injection of a powder dose into the upper or intermediate portions of the pulmonary tract of a subject (i.e., patient). Similarly to embodiments of the subject invention, Century does

disclose a metering chamber of various sizes, as well as a generally single step, gas jet aerosolization mechanism, with "pulsatile air sources or containers of compressed gas."

However, Century's apparatus is a "powder dispenser" for direct pulmonary injection, rather than an aerosol generator whose internal or first stage output is delivery of an expansive bolus to a mixing/stilling/classification chamber for subsequent use. The structural elements and functions are accordingly distinct.

Century uses the word "bolus" at column/line: 7/42, 15/16 & 16/53, 54. Century's bolus is not applicants' expansive bolus and Century does not in any way disclose the concept of an expansive bolus. Moreover, the delivery in Century of aerosols is not expansive but simply transportive. Related to that, Century does not disclose introduction of the output of his system into a mixing/stilling/classification chamber for subsequent use. The patient's lungs cannot be regarded as such a chamber.

European Patent Application EP 0 826 386 (3M) discloses a dry powder medicament dispenser. Similarly to embodiments of the subject invention, 3M employs a metering chamber (or powder pocket, in applicant's terminology), and uses compressed air for aerosolization and, partly, for delivery to the inhalatory flow of a patient. (The other part of the transporting flow is provided by the inhalation flow of the patient.)

3M teaches nothing whatsoever about boli or expansive boli. Nor is there any recitation or disclosure of the introduction of boli into mixing/stilling/classification chambers. Further, in embodiments of the subject invention aerosolization and expansive bolus delivery steps can be

substantially simultaneous; in contrast, like the apparatus in Gerde discussed above, the 3M apparatus implements what is fundamentally a two-step process comprising (1) pressurized aerosolization, and (2) delivery (with some additional aerosolization) via decompression to ambient atmospheric pressure and to the patient, without any form of controls in the mass delivery.

Barrington et al No. 4,184,258 disclose a powder dispenser for dental applications. The Barrington et al device uses gas flows for "blowing powder onto teeth." The gas flows originate with compressed air and the like and simply transport powder from a dosage aperture 24 (column 3, line 1) into a "rigid discharge conduit 25 (column 3, line 4), through a nozzle 26 (column 3,line 60), and onto patient's teeth 32.

Applicant agrees with the Examiner's view that applicant's powder pockets are similar to the Barrington et al "dosage aperture" in that they both accomplish a metering function. However, the similarity ends there. There is no structure in embodiments of the subject invention corresponding to Barrington's discharge conduit and nozzle. The Barrington et al apparatus does not actually aerosolize; it merely transports powder. Further, although not explicitly stated by Barrington et al, likely the particle size of the powder in Barrington et al preferably is non-respirable, to maximize deposition on the teeth and to minimize transport into the patient's respiratory system. In contrast, embodiments of the subject invention do provide for aerosolization, and preferably of respirable particles.

Barrington et al are completely silent on the generation of boli, as well as on the concept of expansive boli.

Blaha-Schnabel No. 5,596,982 discloses an apparatus for drying and buffering (i.e., providing a reservoir) for externally generated aerosols, for inhalalation therapy applications.

At column 3, lines 16-24 Blaha-Schnabel states:

> "In a preferred embodiment, the aerosol is produced by a dispersion nozzle which is introduced into a conically tapering part of the cylindrical apparatus. In this nozzle, a solution and/or suspension is mixed with dry air and sprayed axially in the apparatus. The operating parameters of the nozzle, such as dispersion air humidity, dispersion air throughput and bulk liquid flow, are adapted to the dimensions of the apparatus in such a manner that minimal impaction takes place on the opposite end of the apparatus ..."]

Neither structural elements for the dispersion nozzle or nebulizer (column 1/line 22) nor sufficient aerosol or fluid mechanical parameters nor operational objectives are disclosed by Blaha-Schnabel to enable applicant's expansive boli or applicants' mixing/stilling/classifcation structures or functions. Said expansive boli, when properly integrated with applicants' mixing/stilling/classification chamber, comprises applicants' aerosol generator system, as disclosed and claimed. The Blaha-Schnabel apparatus, as disclosed and claimed, is not an aerosol generator but a separate apparatus which provides post aerosol generation treatment, that is, "... drying and buffering."

Further, Figure 2 of Blaha-Schnabel shows a fundamentally two-step process of filling the apparatus with aerosols and discharging them (after treatment in the apparatus) by patient inhalation. Critical to function of the cited treatment apparatus is cyclone-type flow entry via conduit 5,

Fig 1, which conduit and flow are not required by Applicants' mixing/stilling/classification chamber. The cited apparatus necessarily operates near atmospheric pressure. No disclosure is made for using non-human, separately-driven flows for aerosol delivery.

In view of the application to the field of respiratory therapy, one objective of Blaha-Schnabel is to choose internal volumes to be a fraction of the human inspiratory tidal volumes (~750ml for adults, column 5/line 40) so that one full inhalation by a patient clears the volume. Another objective is to provide sufficient drying of the preferably "wet aerosols" so that the residual solute particle size approaches ~ 5 micrometers, which sizes advantageously reach the alveolar recesses of the lungs and are not deposited within the apparatus or within the upper respiratory tract. Still another objective is to provide flow patterns ("turbulences," possibly better translated from the German as vortices) which minimize internal wall losses. All three objectives enable more efficient use of therapeutic medicaments, as stated.

Accordingly, and consistent with its intended field of use, Blaha-Schnabel is silent on applicants' basic first steps of aerosol generation, which first steps include production of expansive boli, and which are critical and integral elements of applicants' aerosol generation system.

There is no relation between the cited volumes internal to the treatment apparaus and which approximate human tidal volumes, which are of the order of 750 ml, or some fraction thereof, and applicants' expansive boli, whose volumes approximate 1 ml. The apparatus of Blaha-Schnabel, even including its nebulizer input, cannot be considered to be a bolus generator, the output of which would be input to applicants mixing/stilling/classification chamber.

Applicants note that there is an accidental order of magnitude similarity between the cited Blaha-Schnabel apparatus volume and the volume of applicants' mixing/stilling/-classification chamber. However, the functions and structural elements are different, particularly integration with the expansive boli an the input and provision of reasonably constant output aerosol concentrations C and transporting gas flows Q. For example, applicants do not require cyclone flow components via third conduits. Blaha-Schnabel does not provide for external driving or delivery flows to downstream measurement and control elements for controlled delivery, particularly with continuous deliveries. Moreover, applicants' apparatus employs classification or removal of undesireable, large, nonrespirable particles, by sedimentation or wall losses or otherwise, a feature contrary to the objectives of Blaha-Schnabel, particularly including his minimization of wall losses.

Applicants are not claiming the principle treatment aspects of Blaha-Schnabel apparatus, i.e., drying "wet aerosols" to respirable-size, residual solute aerosols and "buffering" (reservoir aspect) them. Applicants are claiming elements for an aerosol generation system which enables formation of dry powder or respirable solute aerosols into "expansive boli", with subsequent introduction or input into a properly-integrated mixing/stilling/classification chamber, and with provision thereby of a reasonably constant mass delivery rate at its output, so that precisely and accurately controlled mass deliveries are achieved. Said expansive boli in applicants' apparatus are generated with higher than atmospheric pressures and with subsequent introduction of said expansive boli into a mixing/stilling/classification chamber where, in fact, well-known drying and reservoir ("buffering" in Blaha-Schnabel) functions can occur.

To summarize before going on to a brief claim-by-claim discussion, applicants submit that the claimed aerosol generation system is novel, said system involving properly integrated combinations of powder or liquid pockets, high velocity gas jets directed into or through them to produce expansive boli, and introduction of the expansive boli into integral mixing/stilling/classification chambers. The subject invention provides, as a penultimate objective, a reasonably constant output for precisely and accurately controlled mass deliveries. It is respectfully submitted that none of the prior art anticipates or enables this primary objective.

Claim 1

Claim 1 stands rejected under 35 USC §102 as anticipated by either Gerde Pat. No. 6,003,512; or Century No. 5,570,686; or EP 0 826 386 (3M); or Barrington et al No. 4,184,258. Reconsideration is requested.

As discussed above, Gerde discloses neither the "expansive bolus" nor the "mixing chamber" of claim 1. Moreover, Gerde does not disclose the "metering pocket" of claim 1.

As discussed above, Century does not disclose an aerosol generator whose internal or first stage output is delivery of an expansive bolus to a mixing/stilling/-classification chamber for subsequent use. Thus, Century discloses neither the "expansive bolus" nor the "mixing chamber" into which boli are introduced for subsequent use, both of which are required by claim 1.

As discussed above, EP 0 826 386 (3M) discloses neither the "expansive bolus" nor the "mixing chamber" into

which boli are introduced for subsequent use, both of which are required by claim 1.

As discussed above, Barrington et al discloses neither the "expansive bolus" nor the "mixing chamber" of claim 1. Moreover, the Barrington et al device is not even an "aerosol generator," only a powder transporter.

Accordingly, none of the applied references disclose the invention of claim 1 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 1 is allowable.

<u>Claim 2</u>

Dependent claim 2 stands rejected under 35 USC §103 as obvious in view of either Century or EP 0 826 386 (3M). Claim 2 recites that the "metering pocket is a micropocket having a volume of the order of one cubic millimeter."

However neither Century nor 3M discloses the "expansive bolus" or the "mixing chamber" into which boli are introduced for subsequent use, both of which are required by claim 1 from which claim 2 depends.

Accordingly, claim 2 is allowable on the basis of its dependency from allowable claim 1.

<u>Claim 3</u>

Dependent claim 3 stands rejected under 35 USC §102 as anticipated by Gerde. Claim 3 recites that the "jet directs gas at a velocity approaching Mach 1 into said metering pocket."

Claim 3 is allowable on the basis of its dependency from allowable claim 1.

Claim 4

Dependent claim 4 stands rejected under 35 USC §102 as anticipated by either Gerde or Century or Barrington et al. Claim 4 recites that the "jet directs gas impulsively into said metering pocket."

Claim 4 is allowable on the basis of its dependency from allowable claim 1.

Claim 5

Dependent claim 5 stands rejected under 35 USC §102 as anticipated by either Gerde or Century or EP 0 826 386 (3M) or Barrington et al. Claim 5 recites that the "jet directs gas continuously into said metering pocket."

Gerde directs gas impulsively, not continuously. Century employs "pulsatile" air sources. Accordingly, neither Gerde nor Century disclose the invention of claim 5 in the identical manner required to support a rejection for anticipation under 35 USC §02. The disclosure of Barrington et al falls far short of applicant's claimed aerosol generator for reasons discussed above.

Accordingly, claim 5 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 1.

Claim 6

Dependent claim 6 stands rejected under 35 USC §102 as anticipated by either Gerde or Century or Barrington et al. Claim 6 recites that the jet directs gas both continuously and impulsively into the metering pocket.

The applied references do not support the rejection of claim 6. Claim 6 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 1.

Claim 7

Dependent claim 7 stands rejected under 35 USC §102 as anticipated by either Gerde or Century. Dependent claim 7 recites that the "jet directs high velocity gas into said metering pocket through a passageway in a wall of said metering pocket."

Claim 7 is allowable at least for the reason that it depends from allowable claim 1.

Claim 8

Dependent claim 8 stands rejected under 35 USC §102 as anticipated by either Gerde or Century or EP 0 826 386 (3M) or Barrington et al. Dependent claim 8 recites that the "jet directs high velocity gas into said metering pocket from outside said metering pocket."

Claim 8 is allowable at least for the reason that it depends from allowable claim 1.

Claim 9

Claim 9 is canceled, since essentially an identical claim is present in Serial No. 09/937,584.

Claims 10-11

Claims 10-11 are allowed.

Claim 12

Independent claim 12 remains rejected under 35 USC §102 as anticipated by Gerde.

First, as discussed above under the heading "Overview of References" and also in the specific context of claim 1, Gerde discloses neither the "expansive bolus" nor the "mixing

chamber" of claim 12. Moreover, Gerde does not disclose the "metering pockets" of claim 12.

Second, and more particularly, claim 12 is directed to the megadose disc embodiment of applicant's FIGS. 8 and 9, and discussed in specification paragraphs numbered [0084] through [0093] as filed ([0088] through [0097] as published). Claim 12 calls for "a megadose disc having a surface and a plurality of metering pockets formed in said surface." There is no such disclosure or suggestion in Gerde, and the Examiner has not pointed to any such disclosure.

Moreover, claim 12 recites "a mechanism for sequentially presenting said metering pockets to the location of a jet." The specification further discusses the characteristics and advantages of this structure, which is far removed from the disclosure of Gerde. Again, there is no such disclosure or suggestion in Gerde, and the Examiner has not pointed to any such disclosure.

Accordingly, Gerde does not disclose the invention of claim 12 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 12 is allowable.

Claim 13

Claim 13 stands rejected under 35 USC §102 as anticipated by Blaha-Schnabel Pat. No. 5,711,292. Claim 13 is directed to an aerosol generator including "an atomizer" which atomizes "a liquid solution of an active ingredient and a volatile solvent." The solution is atomized to produce droplets from which the solvent evaporates to leave an expansive bolus of solute residue.

The Examiner asserts that "Blaha-Schnabel discloses a device a solution of drug and solvent is aerosolized by a gas jet and allowed to expand into a bolus which is caused to dry to

form a solute residue (powder). See col 1 lines 20-37; col. 3 lines 5-20."

However, notwithstanding the Examiner's assertion regarding a "bolus" quoted just above, as discussed above under the heading "Overview of References," Blaha-Schnabel discloses neither the "expansive bolus" nor the "mixing chamber" of claim 13.

Accordingly, Blaha-Schnabel does not disclose the invention of claim 13 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 13 is allowable.

<u>Claims 14-17</u>

Claims 14-17 are also rejected under 35 USC §102 as anticipated by Blaha-Schnabel.

Independent claim 14 is similar to claim 13, but is even more specifically directed to "an aerosol generator for producing aerosols transported by a gas flow <u>at a predictable average mass flow rate</u>." The aerosol generator of claim 14 even more particularly includes "a mixing chamber into which the expansive bolus is delivered, said mixing chamber serving to still the bolus."

Again, as discussed above under the heading "Overview of References," Blaha-Schnabel discloses neither the "expansive bolus" nor the "mixing chamber" of claim 14. Further, there is no disclosure in Blaha-Schnabel of the claimed "predictable average mass flow rate."

Accordingly, Blaha-Schnabel does not disclose the invention of independent claim 14 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 14 is allowable.

Dependent claim 15 recites that the atomizer operates continuously, and is allowable at least for the reason that it depends from allowable claim 14.

Dependent claim 16 recites that "said mixing chamber serves to still and mix the bolus just delivered with boli delivered earlier." There is no such disclosure or suggestion in Blaha-Schnabel.

Accordingly, claim 16 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 14.

Dependent claim 17 is directed to the classification aspect of the mixing/stilling/classification chamber. In particular, claim 17 recites that "there is an upward gas flow within said mixing chamber," and that "the dimensions of said mixing chamber are such that aerosol particles whose Stokes flow settling velocity is higher than the upward gas flow velocity elutriate out. There is no such disclosure or suggestion in Blaha-Schnabel.

Accordingly, claim 17 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 14.

Claim 18

Claim 18 stands rejected under 35 USC §102 as anticipated by either Gerde or EP 0 826 386 (3M) or Barrington et al.

First, as discussed above under the heading "Overview of References" and also in the specific context of claim 1, Gerde, 3M and Barrington et al do not disclose either the "expansive bolus" or the "mixing chamber" of claim 18.

Second, claim 18 is directed to an aerosol generator which produces aerosols "transported by a gas flow at a

predictable average mass flow rate." There is no such disclosure in any of the applied references.

Accordingly, none of the cited references disclose the invention of claim 18 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 18 is allowable.

Claim 19

Claim 19 stands rejected under 35 USC §102 as anticipated by either Gerde or EP 0 826 386 (3M).

Dependent claim 19, like claim 17, is directed to the classification aspect of the mixing/stilling/classification chamber. In particular, claim 19 recites that "there is an upward gas flow within said mixing chamber," and that "the dimensions of said mixing chamber are such that aerosol particles whose Stokes flow settling velocity is higher than the upward gas flow velocity elutriate out. There is no such disclosure or suggestion in the applied references.

Accordingly, claim 19 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 18.

Claim 20

Claim 20 stands rejected under 35 USC §102 as anticipated by Gerde.

First, as discussed above under the heading "Overview of References" and also in the specific context of claim 1, Gerde does not disclose either the "expansive bolus" or the "mixing chamber" of claim 20.

Second, claim 20 is directed to an aerosol generator which produces aerosols "transported by a gas flow at a

predictable average mass flow rate." There is no such disclosure or suggestion in Gerde.

Third, claim 20 is directed to an aerosol generator which includes "a plurality of metering pockets" which are "sequentially" presented to the location of a jet, such as the rotary metering pocket embodiment of FIG. 5 and the megadose disc embodiment of FIGS. 8 and 9. There is no such disclosure or suggestion in Gerde.

Accordingly, Gerde does not disclose the invention of claim 20 in the identical manner required to support a rejection for anticipation under 25 USC § 102. Claim 20 is allowable.

Claim 21

Dependent claim 21 stands rejected under 35 USC §102 as anticipated by Gerde.

Dependent claim 21, like claims 17 and 19, is directed to the classification aspect of the mixing/stilling/-classification chamber. In particular, claim 21 recites that "there is an upward gas flow within said mixing chamber," and that "the dimensions of said mixing chamber are such that aerosol particles whose Stokes flow settling velocity is higher than the upward gas flow velocity elutriate out. There is no such disclosure or suggestion in Gerde.

Accordingly, claim 21 is allowable on the basis of its own recitations, as well as for dependency from allowable claim 20.

Conclusion

Reconsideration and allowance are requested. Claims 10-11 are already allowed. Claims 1-8 and 10-21 are in the case.

Respectfully submitted,

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I hereby certify that this paper is being deposited this date with the U.S. Postal Service as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, under the provisions of 37 CFR 1.8.

Steven C. Schnedler	Dec. 16, 2003
	Date

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